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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/520,401	09/12/2005	Irene Bozzoni	2520-1050	2717

466 7590 06/03/2008

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EXAMINER
RAMIREZ, DELIA M

ART UNIT	PAPER NUMBER
1652	

MAIL DATE	DELIVERY MODE
06/03/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

ADVISORY ACTION

1. Claims 18-21, 35-36 are pending.

2. A requirement for information under 37 CFR 1.105 is hereby made. A requirement for information under 37 CFR 1.105 is discretionary. A requirement may be made at any time once the necessity for it is recognized and should be made at the earliest opportunity after the necessity is recognized. In the instant case, the requirement is now made for the following reasons.

In previous Office actions, the Examiner has repeatedly indicated that the polynucleotide of SEQ ID NO: 1 as originally presented in Figure 4 (1268 nucleotides) is unpatentable under 35 USC 102(b) in view of the teachings of Pietro Laneve (Purificazione e caratterizzazione di una nuova attivita endoribonucleolitica coinvolta nella biosintesi dei piccolo RNA nucleolari in *X. laevis*, Thesis, **2001**; cited in the IDS) as evidenced by GenBank accession number AJ507315 (cited in the IDS). SEQ ID NO: **1 as shown in Figure 4 as originally filed** is identical to the sequence disclosed in the Laneve thesis. See Non Final action mailed on 4/10/2007, item 26, and Final action mailed on 1/8/2008, item 14.

When the application was first examined on the merits, SEQ ID NO: 1 as shown in the sequence listing filed on 1/6/2005 did not match the sequence shown in Figure 4 because SEQ ID NO: 1 in that sequence listing lacks three nucleotides (1265 nucleotides long) and SEQ ID NO: 1 in Figure 4 had 1268 nucleotides. This was promptly indicated to Applicant by the Examiner. See Non Final action mailed on 4/10/07, item 4. The three nucleotides missing belonged to a non-coding region at the 3' end. Since some of the claims were directed in part to a nucleic acid encoding the polypeptide of SEQ ID NO: 2, the teachings of the Laneve thesis were still considered anticipatory. In response to the Non Final action mailed on 4/10/2007, Applicant traversed the rejection on the grounds that GenBank accession number AJ507315 was published after the filing date of the foreign priority document (7/8/2002) even though the Office action clearly stated that the rejection was being made in view of the teachings of the Laneve thesis.

This was also indicated in the Final action mailed on 1/8/2008, item 14. Applicant **did not amend SEQ ID NO: 1** to match what was originally disclosed in Figure 4. The amendment filed on 10/10/2007 changed the scope of the claims such that they encompassed only nucleic acids comprising/consisting of SEQ ID NO: 1 and vectors thereof. Since SEQ ID NO: 1 as shown in the sequence listing was not identical to the nucleic acid of the Laneve thesis (1268 vs. 1265 nucleotides), the Examiner **withdrew** the rejection over the Laneve thesis and advised Applicant that if SEQ ID NO: 1 were to be amended to be that shown in Figure 4 as originally filed, **the 35 USC 102(b) and 103(a) rejections made in the Non Final action of 4/10/2007 would be reintroduced** (items 14 and 19 of the Final action). In response to the Final action, Applicant has amended SEQ ID NO: 1 such that it now discloses the sequence as originally presented in Figure 4. Thus, the previous rejections under 35 USC 102(b) and 103(a) are necessitated by applicant's amendment. Applicant argues in the response filed on 5/8/2008 that the Laneve thesis is not proper prior art because the thesis was presented at a University in Italy and that the invention was not patented or described in a printed publication in this country or foreign country, or in public use or on sale in this country, more than a year prior to the date of the application for patent in the United States. Applicant provides no evidence to show that a thesis which was available in 2001, **two years before the filing date of the international application** (PCT/IT03/00424), was not **publicly** available prior to the filing date of the international application, or when was the thesis first available to the public. It should be noted that a thesis is not considered an oral disclosure but a printed document. This is evidenced by the fact that GenBank accession number AJ507315 discloses the Laneve thesis as the reference corresponding to that entry. As known in the art, references disclosed in GenBank entries are printed references.

Since it is common practice in universities to place copies of theses originated from their own departments in their libraries, one would assume that the Laneve thesis was placed in a

library in the corresponding Italian university (Universita La Sapienza, Rome) for others to browse. The author of the Laneve thesis is inventor Pietro Laneve. Therefore, the Examiner hereby requests from Applicant **the earliest date when the thesis by inventor Pietro Laneve was first placed in a library or bookshelf for public browsing. This includes not only main libraries but departmental libraries or any place where the thesis could have been accessible to the public**. This information is essential to determine whether prior art rejections should be maintained or withdrawn. **It was not previously requested because the date when the Laneve thesis was first available to the public was not an issue until the response filed by Applicant on 5/8/2008.** Since inventor Pietro Laneve is the author of the cited prior art, he is in better position to obtain/provide the requested information. It should be noted that the USPTO has attempted to obtain this information from Universita La Sapienza (Rome) but such attempts have been unsuccessful. Initially, librarians at the Universita La Sapienza (Rome) indicated to the library at the USPTO that the request for information was being forward to Dr. Laneve and that he would contact the library at the USPTO. Later, librarians at Universita La Sapienza (Rome) indicated to the library at the USPTO that this information is not being provided because the material in that thesis is the subject of a patent application.

3. The request for entering amendments to the sequence listing and claims 20-21, and arguments filed on 5/8/2008 under 37 CFR 1.116 in reply to the Final Action mailed on 1/8/2008 are acknowledged. The proposed amendments to the claims will be entered and an explanation as to how the claims would be rejected is provided below. While amendments to the claims and the sequence listing seem to overcome the objections, and 35 USC 112, first paragraph, rejections previously applied, the proposed amendments now require the reintroduction of 35 USC 102(b) and 35 USC 103(a) rejections previously applied in the Non Final action mailed on 4/10/2007. It should be noted that the Examiner indicated to Applicant that these rejections would be

introduced if SEQ ID NO: 1 were to be amended as disclosed in Figure 4 as originally filed. See Final action, items 14 and 19.

4. Claims 19 and 35 would be rejected under 35 U.S.C. 102(b) as being anticipated by Laneve, P. (Purificazione e caratterizzazione di una nuova attivita endoribonucleolitica coinvolta nella biosintesi dei piccolo RNA nucleolari in *X. laevis*, Thesis, 2001; cited in the IDS) as evidenced by GenBank accession number AJ507315 (cited in the IDS). Claims 19 and 35 are directed to any nucleic acid comprising or consisting of SEQ ID NO: 1. GenBank accession number AJ507315 discloses the nucleotide sequence of mRNA encoding a *X. laevis* protein and indicates Laneve, P. as the reference corresponding to the nucleotide sequence disclosed. The mRNA of Laneve, P. (1268 nucleotides long) is identical to the polynucleotide of SEQ ID NO: 1. See alignment attached. Therefore, the teachings of Laneve, P. anticipate the instant claims as written.

5. Claims 20-21 would be rejected under 35 U.S.C. 103(a) as being unpatentable over Laneve, P. (Purificazione e caratterizzazione di una nuova attivita endoribonucleolitica coinvolta nella biosintesi dei piccolo RNA nucleolari in *X. laevis*, Thesis, 2001; cited in the IDS). The teachings of Laneve, P. have been discussed above. Laneve, P. does not teach an expression vector which can be used in prokaryotic or eukaryotic cells for expression of the *X. laevis* protein.

Claims 20-21 are directed to vectors comprising the nucleic acid of claim 19 as described above wherein said vectors can be used in prokaryotic or eukaryotic cells for expression of the protein encoded by the polynucleotide of SEQ ID NO: 1.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to make an expression vector comprising the nucleic acid of Laneve, P. that can be expressed in prokaryotic or eukaryotic cells. A person of ordinary skill in the art is motivated to construct such a vector and express the nucleic acid of Laneve, P. for the benefit of recombinantly producing the *X. laevis* protein encoded by said nucleic acid to obtain sufficient

amounts of the *X. laevis* protein for further characterization. Recombinant production of proteins is generally considered a preferred method for obtaining a protein since it can potentially produce larger amounts of the product in a consistent fashion, as opposed to isolation from the natural source. In addition, a person of ordinary skill in the art is motivated to construct vectors that can be used in prokaryotic cells because recombinant production of proteins in prokaryotic cells is usually faster, easier and less expensive. A person of ordinary skill in the art is motivated to construct vectors that can be used in eukaryotic cells because prokaryotic cells cannot perform post translational modifications. One of ordinary skill in the art has a reasonable expectation of success at making the vectors because construction of expression vectors to be used in prokaryotic and eukaryotic cells is well known and widely used in the art. Therefore, the invention as a whole would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made.

6. Applicant argues that these rejection should not be reintroduced because the thesis was presented at a university in Italy and that the invention was not patented or described in a printed publication in this country or foreign country, or in public use or on sale in this country, more than a year prior to the date of the application for patent in the United States. Applicant also argues that the thesis is an oral reference. These arguments are not persuasive. There is no evidence to show that a thesis which was available in 2001, **two years before the filing date of the international application** (PCT/IT03/00424), was not **publicly** available in Italy or somewhere else prior to the filing date of the international application. There is no disclosure of when was the thesis first available to the public. As indicated above, it is customary in universities to place theses and dissertations from those universities in their local libraries. Therefore, one would expect a thesis that was available sometime in 2001 (according to GenBank) to be placed in a library a few months after. Also, it should be noted that a thesis is not considered an oral disclosure but a printed document. This is evident by the fact that GenBank

accession number AJ507315 shows the Laneve thesis as the reference corresponding to the sequence of that entry.

7. For purposes of Appeal, the status of the claims is as follows

Claim(s) allowed: NONE

Claims(s) objected to:

Claim(s) rejected: 19-21 and 35

Claim(s) withdrawn from consideration: 18, 36

8. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PMR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Delia M. Ramirez whose telephone number is (571) 272-0938. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Nashaat Nashed can be reached on (571) 272-0934. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

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DR
June 3, 2008